To: Office of Attorney General
AGO.highcostprescriptiondrugs@vermont.gov

From: Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Road
Morgantown, WV 26505

Date: July 1, 2021

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on June 3, 2021 Mylan Pharmaceuticals Inc. ("Mylan") provided written notice to the Office of the Attorney General that it introduced new generic prescription drugs, Rufinamide Tablets USP, 200 mg and Rufinamide Tablets USP, 400 mg, ("the Products"), to the commercial market on June 1, 2021 at a wholesale acquisition cost that is over the threshold set for a specialty drug under the Medicare Part D program.

This letter provides the additional required information by 18 V.S.A. § 4637(c) regarding the Products. Mylan notes that the Office of the Attorney General has not yet prescribed a format for submissions under this section. Further, as authorized by 18 V.S.A. § 4637(d), Mylan has limited the information reported to that which is in the public domain or publicly available.

(1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;

Rufinamide tablets are indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in pediatric patients 1 year of age and older and in adults. The Wholesale Acquisition Cost (WAC) for the product in the United States is below:

NDC	Products	Package Size	WAC
0378-2330-78	Rufinamide Tablets USP, 200 mg	120	$1,367.06
0378-2331-78	Rufinamide Tablets USP, 400 mg	120	$2,734.11

The prices negotiated with customers as well as any marketing plans in the United States or internationally are confidential and not in the public domain or publicly available. In the United States, Mylan sells its products directly to wholesalers, distributors, retail pharmacy chains, long-term care facilities and mail order pharmacies. Mylan also sells its generic products indirectly to several entities, including independent pharmacies, managed care organizations, hospitals, etc. These customers, called "indirect customers," purchase our products primarily through our wholesale customers.

(2) the estimated volume of patients who may be prescribed the drug;

No information specific to the estimated number of patients that may be prescribed Mylan's Products is in the public domain or publicly available.

(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval;

The Products were not granted breakthrough therapy designation or priority review by the FDA.

(4) the date and price of acquisition if the drug was not developed by the manufacturer.

The Products were not the result of an acquisition.